Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

This guidance is being distributed for comment purposes only.

Computed Imaging Devices Branch
Division of Reproductive, Abdominal,
Ear, Nose, Throat and Radiological Devices
Office of Device Evaluation

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Comments and suggestions regarding this draft document should be submitted within 45 days of the date of the Notice of Availability published in the Federal Register. Submit comments to Robert A. Phillips, Ph.D., HFZ-470, at the address below. Comments and suggestions received after this date may not be acted upon by the Agency until the document is next revised or updated. For questions regarding this draft document, contact Dr. Phillips at (301) 594-1212.

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Food and Drug Administration
Center for Devices and Radiological Health
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510(k) DIAGNOSTIC ULTRASOUND CHECKLIST

510(k) Number:
Device Name:
Company Name:

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SECTION	**ITEM**	**PRESENT** Yes	No	**NEEDED** (Y/N/?)
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SECTION	**ITEM**	**PRESENT** Yes	No	**NEEDED** (Y/N/?)
2	**LABELING**			
2.1	Draft Acoustic Output Tables	___	___	_____
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INTRODUCTION

This updated guidance is intended to assist the manufacturer in preparing a well organized, concise, and complete 510(k) premarket notification submission to the Center or a third-party reviewing organization. The following are some key elements for consideration:

- The Center will make decisions concerning 510(k) submissions for diagnostic ultrasound devices based on a single submission. The 510(k) submission should contain all the information requested in Sections 1-7 of this Guidance (see 510(k) Diagnostic Ultrasound Screening Checklist, pages 4 and 5). All information that requires measurement, calculation, validation, or testing may be derived from prototype devices, unless stated otherwise herein. Information that is provided by reference should supply a specific document number and page.

  Substantial equivalence decisions must be followed by the submission of a post-clearance special report, hereafter referred to as the “510(k) Special Report,” providing production acoustic output values and other information. The 510(k) Special Report must be submitted prior to shipping the first device (prior to first customer shipment). It may be included with the original 510(k) submission (please note choice in your cover letter). The manufacturer, distributor, or importer should submit the 510(k) Special Report (Appendix G) as an “add-to-file” and should reference the manufacturer's 510(k) number.

  A manufacturer may not ship a diagnostic ultrasound device until a 510(k) clearance letter is received from FDA and the 510(k) Special Report is submitted. If a manufacturer ships a device without first receiving 510(k) clearance and submitting the 510(k) Special Report, the manufacturer will be in violation of the Food, Drug, and Cosmetic Act. If the 510(k) Special Report is incomplete or contains unacceptable values (e.g. acoustic output greater than the approved levels), then the 510(k) clearance may not apply to the production units, which then may be considered adulterated or misbranded.

  There are two exceptions to the above paragraph: 1) Refurbished devices are exempt from 510(k) submission but not from Initial Report submission. In this case, the Special 510(k) Report should be submitted in lieu of the Initial Report. 2. An investigational device may be shipped prior to receiving a 510(k) clearance. Again, a Special 510(k) Report should be submitted in lieu of the Initial Report.

  Manufacturers submitting a 510(k) are exempted from submitting an Initial Report under 21 CFR 1002.10 and 1002.12 (Appendix F) for ultrasonic products. Manufacturers are not exempted from the requirements of 21 CFR 1020.10 (Performance Standard for Television Products and subsequent reporting), 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair, or Replacement of Electronic Products).

- The 510(k) regulation requires the submission of a new notification for devices already in distribution when the device is significantly changed or modified (21 CFR 807.81(a)(3)). The regulation defines the following

changes as significant:

1. a change that could significantly affect safety or effectiveness, e.g., a significant change in design, materials, energy source, specification or manufacturing; or

2. a change in intended use.

The submitter should refer to the CDRH guidance document titled “Deciding When to Submit a 510(k) for a Change to an Existing Device” (CDRH, 1997) for guidance in this area.

The Center will respond to inquiries concerning the need for a new 510(k). These inquiries should be in writing and in sufficient detail so that the Center can make a judgement about the need to submit a 510(k) (See Appendix E).

Note: FDA regulates diagnostic phantoms, QA test objects, and other devices used to test diagnostic ultrasound systems and transducers as Class I Radiologic Quality Assurance Instruments (21 CFR 892.1940). Such devices are exempt from the requirement of 510(k) premarket notification.

A refurbished device, not subject to a new 510(k) submission, must have a Abbreviated Initial Report (similar to Appendix G) submitted under 21 CFR 1002.12.

- This guidance retains the two-track approach to marketing clearance, Track 1 and Track 3. Track 1 is for devices that do not follow the Output Display Standard and therefore have application-specific limits; Track 3 is for devices that conform to the Output Display Standard. There is no Track 2.

- Track 1 submissions for devices whose overall acoustic output exceeds application-specific limits (Track 1, Sec. 3) should be supported by laboratory and clinical data demonstrating the need for higher output. These submissions should describe what user-interactive features are provided to enhance user awareness of acoustic output (e.g., on-screen display, power-up default settings, manual override).

- Statistical analyses of measurement or performance data are requested in several sections of the Guidance. See Appendix D for a summary.

1 BASIC INFORMATION:

The submission should contain a cover letter and a contents page; the major sections of the submission should be tabbed and the numbering scheme should follow this Guidance. The labeling should follow the format provided in Appendix D.

The submission should contain the following:

1.1 Manufacturer's Name:
Address:
Corresponding Official: Title:
Address:
Telephone:

1.2 U.S. Agent (if manufacturer is overseas)
Name/Title/Firm:
Address:
Telephone:

1.3 Importer Name:
Address:
Contact Person: Telephone:

1.4 Device Name:

1.5 Common Name:

1.6 Classification Regulatory Class: II Review Category: Tier II

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Other		

1.7 Establishment Registration Number:

1.8 514 Performance Standards: None

1.9 Special Controls: 510(k) Special Report

1.10 Prescription Status: Prescription Device

1.11 Manufacturing Location and Sterilization Sites:

1.12 Reason for Submission:

1.13 Identification of the TRACK being followed for the submission (Track 1 or Track 3). The cover letter should indicate if the 510(k) Special Report is included as a separate part of the submission or if it will be submitted in the future.

For all 510(k) submissions, as a separate section, you should provide either 1) a “summary of safety and effectiveness” of that information that supports an equivalence determination or 2) a statement that the information supporting an equivalence determination will be made available, by you, upon request (see Appendix C). In addition you should submit a "Truthful and Accurate Statement" and on a separate sheet, the indications for use for your device (see Appendix C and note that the exact wording must be used).

2 INDICATIONS FOR USE

Identify all indications for use (new and previously cleared) of the subject device (fill out the indications for use form(s) or equivalent, Appendix C, one for the system and one for each transducer). Include 510(k) control numbers for the previously cleared indications.

3. GENERAL DEVICE DESCRIPTION

3.1 Provide a general description of the subject device, including (but not limited to) model designation, design, patient contact materials, control panel, and system operation. The following items should be addressed for system operation (as applicable):

3.1.1 Describe the transducer operation in each mode and mode combination, including, but not limited to:

a. the type of transducer (e.g. model designation, mechanical sector, rectangular phased array, curved linear array, annular phased array);

b. size and spacing of element(s), geometrical configuration, total number of elements in the array and array dimensions, as well as the maximum number of active elements for a single pulse, where applicable, and the nominal ultrasonic frequency(ies) of the transducer assembly.

3.1.2 Describe the operating controls that can cause a change in the radiated field, e.g., gain, pulse repetition frequency, transmit focal length, sector angle, image rate, pulse duration, depth, and sample volume. For a Track 1 device, describe the operating controls and procedure necessary to change to an application or mode that has a higher application-specific acoustic output limit.

3.1.3 Describe any unique features or technological characteristics of the subject device. Please refer to Appendix E, which discusses 3-D and amplitude Doppler, for examples of the type of information to be submitted.

3.1.4 In submissions for a new transducer or a new indication for an existing transducer, provide summary information for all transducers cleared for use with the system, their indications, their mode, their maximum output, and the 510(k) control number of the submission(s) where they were cleared.

3.1.5 Specify which track is followed in the 510(k) submission. Systems

may use transducers that are of different tracks, but a single transducer should be either Track 1 or Track 3 for all applications with a specific model. In some cases, however, exceptions may be considered (e.g., transcranial Doppler (TCD)).

4 PREDICATE DEVICE COMPARISON

4.1 Identify comparable predicate device(s) to which the subject device is being claimed substantially equivalent. Identify, if possible, the control number(s) of the 510(k) premarket notifications for the predicate device(s).

4.2 The subject device should be compared to the predicate device(s), in terms of key safety and effectiveness features. Discuss the differences and provide supporting data, where applicable. Provide the following (in tabular format wherever possible):

- -indication(s) for use;
- -general device description (design, patient contact materials, operational characteristics, specifications);
- -acoustic output and device settings used;
- -general safety and effectiveness; and
- -labeling and/or promotional materials (draft documents are acceptable)

4.3 Identify any accessories or kits intended for use with the device. For these accessories or kits, provide evidence of the predicate status of the designated comparison device(s); i.e., pre-Amendments or 510(k) control number(s). Provide kit certification.

5 ACOUSTIC OUTPUT REPORTING

Defined below are the "tracks" a manufacturer of diagnostic ultrasound equipment may follow to demonstrate the substantial equivalence of its ultrasound system with respect to acoustic output. In all cases, the derated maximum acoustic output may not exceed pre-Amendments upper limits; i.e., derated $I_{SPTA} \leq 720$ mW/cm^2 and either MI ≤ 1.9 or derated $I_{SPPA} \leq 190$ W/cm^2. Note that the maximum derated value is the maximum value after derating, and not the derated value corresponding to the maximum value measured in water.

In all submissions, the manufacturer should certify that the acoustic output will be or was measured and calculated per the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD 2-1992, Revision 1, December 7, 1993)**UPDATE AFTER AIUM**. Any deviation from the methodologies outlined in NEMA guidance documents should be fully described in terms of the differing methodology used and validating data.

In determining the maximum acoustic output, manufacturers are not expected to include hydrophone measurement uncertainties when reporting intensity or MI values, because measurement uncertainties were not included in the guidance levels in the table in Track 1, Sec. 3. To further clarify this reporting procedure, the uncertainty of the guidance limits is estimated to be $\pm$30% for intensity and $\pm$15% for MI, so a firm does not have to account for its measurement uncertainty as long as that uncertainty does not exceed 30% (or

15%). If the measurement uncertainty does exceed 30% (or 15%), then the guidance values should be reduced accordingly by the amount over 30% (or 15%).

For example, if the maximum hydrophone-determined $I_{SPTA.3}$ was 600 mW/cm^2, and the hydrophone measurement uncertainty for intensity was ±25%, then the value 600 mW/cm^2 (and not 600x1.25 = 750 mW/cm^2) would be compared to 720 mW/cm^2. However, if the hydrophone uncertainty was ±35%, then 600 mW/cm^2 would be compared to 720x .30/1.35) = 693 mW/cm^2.

As part of the Device Master Record, Design History File, and Device History Record (21 CFR 820.181, 820.30(j), and 820.184), manufacturers will be responsible for keeping complete documentation of the acoustic output measurement of their transducers. Documentation should include measurement instrumentation & calibration, software, and test results & test protocols. Acoustic output measurements will be performed according to the sampling plan described in the 510(k) Special Report and compliance will be evaluated as part of Good Manufacturing Practices (GMPs).

5.3 Test Methodology Reporting

Provide in the 510(k) either (I) a separate section containing a description of the acoustic output test methodology, or (ii) reference to a previously cleared 510(k) or PMA submission that contains an acceptable description of the acoustic output test methodology (include 510(k) or PMA number along with attachment number and/or page numbers). In the latter case, any updates to the test methodology that could affect the comparison with the predicate device should be specifically noted and included in the submission. The test methodology section should contain the following components:

5.3.1 Description of measurement instrumentation (e.g., hydrophone type, effective diameter, frequency response, hydrophone amplifier characteristics). Include manufacturers' names and model numbers for commercial devices.

5.3.2 Description of measurement set-up.

5.3.3 Description of measurement and calculation procedures, including consistency checks and protocol for assuring that maximum output conditions are identified, especially in auto-scanning and combination-mode situations.

5.3.4 Description of company protocol for assuring that when either hardware or software changes are made, the effects of these changes on the acoustic output are assessed, and, if necessary, are then measured, documented, and incorporated into the labeling and, if applicable, output display.

5.3.5 Description of any procedures used to correct for spatial averaging by the hydrophone, if applicable. (See, e.g., B. Zeqiri and A.D. Bond,"The influence of waveform distortion on hydrophone spatial-averaging corrections - Theory and measurement," J. Acoust. Soc. Am. 92,1809-1821, 1992.)

5.3.6 Description of calibration procedures for measurement instruments.

5.3.7 Assessment of systematic and random uncertainties associated with measurement or calculation of the ultrasonic power, pressure, intensities, and center frequency, including a brief description of all relevant error sources considered and an explanation of how the overall uncertainty was determined. See Appendix D, item 2.

5.3.8 Description of protocol for assuring substantial equivalence to a predicate device regarding acoustic output (e.g., reject limits in production in comparison to output levels in Track 1, Sec. 3). If 100% testing is performed, confirm that the test protocol in 5.3c above is used or describe the correlation between acoustic output and sensitivity or other measurable parameter(s). If 100% testing is not performed, include a description of the statistical sampling plan used to ensure that production units will not exceed the maximum acoustic output limits specified in the guidance. Typically this plan will comprise the one-sided tolerance limit for normal distributions. See Appendix G, Sec. E6. For this plan, provide the values of γ and P.

5.3.9 An example calculation of the I(SPTA.3) in both a non-auto-scanning and auto-scanning mode, including a pictorial representation of the hydrophone voltage waveform(s).

6 GENERAL CLINICAL SAFETY & EFFECTIVENESS

6.1 Clinical Measurement Accuracy and System Sensitivity

6.1.1 Identify and describe the various clinical (biometric) measurements that may be performed with the subject device.

6.1.2 For each transducer/mode combination, give the accuracy of any measurement (e.g., distance, volume, heart rate, Doppler frequency shift, velocity, indices, etc.) that can be made in that mode, and the range over which this accuracy can be expected to be maintained. Describe and justify the test methodology (e.g., laboratory phantom) used to determine each accuracy. With regard to Doppler accuracy, please note that electronic phantom data are not acceptable. One example of an acceptable test is to use a Doppler string phantom, and to provide a plot for each transducer of measured versus actual velocity with error bars for at least ten velocity values over the range of velocity values specified in the labeling.

6.1.3 For each probe, mode combination, a minimum performance specification of the Doppler sensitivity, where the Doppler sensitivity is defined according to Appendix A, shall be provided in the 510(k). Data validating the specification shall be included in the Device Master Record and submitted in the 510(k) Special Report. For certain special cases or claims, clinical data or special phantom testing may be more appropriate.

6.2 Thermal, Mechanical, and Electrical Safety

6.2.1 Provide either third party certification, indication that third party certification will be achieved prior to marketing, or data showing that your system has been designed to be thermally, electrically, and mechanically safe. You may include descriptions, safety precautions, testing and data to support the electrical and mechanical safety of your device and identify applicable voluntary standards to which the system conforms or supply third party certification that your device meets an acceptable standard. We recognize IEC-601-1, UL-2601 (future), UL544 (electrical only), CSA C22.2 No. 125 (electrical only), and BSA 5724 (electrical only).

6.2.2 For invasive probes, describe the means used to limit the surface heating of probes (e.g. thermal shutdown for a transesophageal probe) and the limiting temperature in the event of a malfunction (e.g. runaway power).

6.3 Patient Contact Materials

6.3.1 Provide the name and chemical composition of all patient contact materials or provide the Master File number that contains the material description.

6.3.2 Provide biocompatability data according to the ISO-10993 Standard for any patient contact materials. For materials, probes, components and accessories that have been previously cleared for the same or more critical tissue contact, biocompatability data need not be provided if the sponsor certifies that the patient contact materials are unchanged in formulation and processing from the previously cleared device.

6.4 Cleaning, Disinfection, Sterilization, and Pyrogenicity

6.4.1 If the transducer is supplied non-sterile or is intended to be reused, provide recommended procedures to clean and disinfect the transducer between uses. These recommended procedures should be validated by you and a summary of your validation procedures provided in the submission (see Appendix H). Alternatively, you may recommend the use of a cleared liquid sterilant or disinfectant product with instructions to follow the labeling.

a. The level of disinfection or sterilization should be appropriate for the intended clinical use. Indicate the target sterility assurance level (SAL) that should be reached by following the recommended procedures.

b. Any recommended disinfecting or sterilizing agents must be registered with the Environmental Protection Agency (EPA) and approved by FDA.

6.4.2 For device components or accessories provided sterile to the user, provide the following information:

a. the method of sterilization and a description of the method used to validate the sterilization cycle;

b. the SAL (sterility assurance level) intended (at least 10^{-6}) for the device;

c. a description of the packaging system used to maintain device sterility;

d. if the device is sterilized using ethylene oxide, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin and ethylene glycol; and

e. if the device is radiation sterilized, the radiation dose used to achieve sterility.

6.4.3 If the device is labeled pyrogen-free, provide a description of the method (standard method) used to assess pyrogenicity. Probes and sheaths that contact brain tissue must be pyrogen free.

6.5 Software/Firmware

Software that governs the operation of diagnostic ultrasound equipment is a minor level of concern, as described in its "Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review" (August 29, 1991). The rationale for this is the potential for injury possible to a patient in the event of software/firmware failure, both direct (i.e., inappropriate delivery of electrical, thermal, or acoustic energy) and indirect (i.e., inappropriate physician action based on inaccurate diagnostic information), is not likely to be major or life threatening.

Provide a full description of the software/firmware supporting the operation of the subject device per FDA's Reviewer Guidance, commensurate with the minor level of concern. This guidance applies to original systems, as well as to any software/firmware changes made to already-marketed devices. Changes to software should be revalidated and reverified. FDA recognizes that many of these ultrasound systems have a variety of software modules controlling many different functions, and that the level of concern for a particular module may vary. With appropriate justification, a manufacturer may provide different levels of documentation for different modules.

Your 510(k) submission should provide the following:

1. a summary description of new or altered algorithms and explain why they are suitable for the chosen task;
2. the software version number;
3. a software structural chart;
4. a system hazard analysis;
5. A listing of the specific hardware/software requirements;
6. a summary of the software design and development process including the software change management process;
7. a summary of software verification and validation processes; and
8. a summary of what future testing will demonstrate and what has been completed up to the time of the submission.

7 LABELING

7.1 Provide draft operator's manuals and any promotional materials that describe the system and associated transducers (maintenance manuals, etc. are not necessary). Labeling for all diagnostic ultrasound equipment should comply with 21 CFR 801.109. Manufacturers are encouraged to consult with FDA's manual, "Labeling: Regulatory Requirements for Medical Devices", (HHS Publication FDA 89-4203). In general labeling should contain: a description of the device, indications for use, contraindications, warnings, precautions, adverse effects, instructions for use, summaries of clinical studies, and references.

7.1.1 Indications for use, contraindications, warnings, and precautions should be clearly stated. This includes (but is not limited to):

a. a prescription statement: "Caution-Federal law restricts this device to sale by or on the order of a physician";

b. a precaution to perform a given ultrasound procedure prudently using the principle of ALARA (as low as reasonably achievable); and;

c. a statement, where applicable, cautioning that the device is "not intended for fetal use" (either in the operator's manual, individual transducer manuals, or on-screen labeling); and

d. a description of thermal cut-outs where applicable.

At present, you may not promote or market your device for use in the following clinical applications:

- percutaneous umbilical blood sampling (PUBS)
- in vitro fertilization (IVF)

Specific diagnostic claims must be supported by appropriate data.

For new clinical or technological changes, it is advisable to check with the Office of Device Evaluation for guidance on the data necessary to support such changes.

7.1.2 Clinical instructions for the use of the device should be provided in either the system or transducer operator's manual. Indications for use should be specified.

7.1.3 Identify the device's compatible device accessories, kits and components in the operator's manuals. Provide the specifications for these accessories. Where use of probe sheaths is recommended, the user should be referred to FDA's March 29, 1991, Medical Alert on latex products.

7.1.4 Provide the accuracy of each clinical measurement possible with the device and the range over which this accuracy can be expected to be maintained. Note that the accuracy range possible for Doppler applications cannot exceed the range measured under 6.1.2.

7.1.5 Provide Draft Acoustic Output Labeling in the operator's manual, per Track 1, Sec. 2 or Track 3, Sec. 2.

7.1.6 Provide instructions for care of the device between uses, including storage, cleaning, disinfection, and sterilization of all components, as appropriate.

a. Labeling should indicate that the use of market-cleared probe sheaths, sterile when appropriate, are recommended for clinical applications of an invasive nature (i.e. intra-operative, transrectal/vaginal, transesophageal, biopsy procedures).

b. When recommending a procedure that uses a cleared liquid disinfecting or sterilizing agent, refer the user to the labeling instructions provided by the manufacturer of that product. At least one recommended procedure should use a cleared agent, if feasible. The ultrasound manufacturer will not need to validate these processes if they refer the user to the manufacturer's instructions.

c. When recommending a procedure other than liquid disinfection or sterilization, detailed instructions should be provided. These procedures should have been validated and a summary of the validation process and representative data submitted as part of the 510(k) submission.

d. When recommending a procedure for intraoperative neurosurgical applications (i.e., when the probe makes contact with the dura or any intracranial tissues) either supply evidence that the probe is sterile and pyrogen-free or high-level disinfected when used with a sterile pyrogen-free sheath. An additional caution should warn the user of a problem in using the probe on patients with Creutzfeld-Jacob disease. If the probe is contaminated, it may have to be destroyed since it cannot be adequately disinfected.

7.1.7 Additional labeling may be necessary to address safety and effectiveness concerns, depending upon the clinical application(s) of that transducer, e.g., transcranial, transesophageal, intravascular, intraoperative, transvaginal, ophthalmic, vascular diagnostic systems, etc. Neurological intraoperative probes should be pyrogen-free, should not be sterilized using liquid Sterilants, should contain a warning concerning Creutzfeld-Jacob disease, and should be used with sterile, pyrogen-free sheaths.

7.1.8 References to literature may be included, where appropriate. (Note that techniques, methods, and indications given in such literature may represent intended use(s) of the subject device and may need to be supported by clinical data.)

TRACK 1 SPECIFIC INFORMATION

Track 1 is for diagnostic ultrasound systems that do not conform to the Output Display Standard or are not indicated for any fetal Doppler applications (except for fetal heart rate monitors, Sec. 1.3). Track 1 submissions are evaluated in relation to application-specific acoustic output limits. Systems that exceed application-specific limits are evaluated on a case-by-case basis. See Sec. 4 for a logic flow chart.

1 Track 1 Acoustic Output Reporting

Track 1 reporting is based on application-specific comparisons to pre-Amendments output levels given in Track 1, Sec. 3. Measurements for each transducer should be made at the highest output setting available for use. Note: For each transducer, the system should operate in such a way that a conscious and deliberate action is required to change to an application or mode that has a higher application-specific acoustic output limit. Otherwise, output measurements should be made for the application having the highest application-specific limit. (See General Information, Sec. 3.1.2.)

1.1. Summarize the mode/application possibilities for each system/transducer combination by completing the table given in Sec. 5. For each possible mode/application identified, specify the target range of values for the MI or I(SPPA.3) and I(SPTA.3) under the operating conditions that maximize these quantities, noting that the upper bound must not be greater than the appropriate application-specific value listed in Sec. 3. Also provide the engineering basis for the range of values specified (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers).

1.2 If the manufacturer wishes to submit the 510(k) Special Report as part of the 510(k), it should be included as a completely separate section and this election should be noted in the 510(k) cover letter. The 510(k) Special Report should follow the format described in Appendix G.

1.3 This guidance amends Section VI of the 1985 output reporting guidance document regarding continuous fetal heart rate (FHR) monitoring with low-power unfocused CW Doppler transducers. The pre-1976 I_{SATA} at the transducer face is 20 mW/cm^2 for CW Doppler FHR monitors. A simple conservative approach for pulsed Doppler FHR monitors is to use 20 mW/cm^2 as a limit for the I_{SATP} at the transducer face. For such transducers, two estimates are made:

a) Duty Factor (DF) = Pulse Duration X Pulse Repetition Frequency

b) I_{SATA} @ Transducer Face = Ultrasonic Power ÷ Area Corresponding to Entrance Beam Dimensions

If the I_{SATA} @ Transducer Face ÷ DF is less than 20 mW/cm^2, then the transducer's acoustic output is below pre-Amendments levels for this

type of ultrasound transducer, i.e., 20 mW/cm^2. If this value is higher than 20 mW/cm^2, you may consult with CDRH about the appropriate measurements that need to be made.

1.4 For any transducer intended for transcranial (cephalic) applications, in which the $I_{SPTA.3}$ exceeds 94 mW/cm^2, provide an estimate of maximum temperature rise (TR) attributable to the use of that transducer for each operating mode. Describe the model used to determine the estimation. This model should account for heating of skull bone. An acceptable model for making these estimates can be found in Section 6 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices." Note that the special labeling will require on-screen precautions about scanning through the eye, burr-holes, fontanelles, or foramen magnum.

2 Track 1 - Acoustic Output Labeling in the Operator's Manual

2.1 Provide tables of the maximum acoustic output values for each possible system/transducer/mode/application combination, per Sec. 5 and 6. The tables for the 510(k) submission need not be completed, but the different table formats (e.g., non-auto-scanning mode, auto-scanning mode) to be used should be submitted, along with the description of symbols. The labeling (submitted in the 510(k) Special Report) for the marketed device, however, should contain the full set of complete acoustic output tables, along with the corresponding operating conditions and the measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency).

2.2 Provide an explanation of how derated intensities were derived from intensities measured in water.

2.3 Provide an explanation of the interactive system features that affect acoustic output (see General Information, Sec. 3.1.2). Provide suggestions on how to use these features to follow the ALARA principle. For transducers that exceed application specific acoustic output limits, or for transducers for which more than one application-specific acoustic output limit applies, describe what user-interactive features are provided to enhance user awareness of acoustic output (e.g., on-screen display, power-up default settings, manual override, warnings).

3 Pre-Amendments Acoustic Output Levels

The following are the highest known acoustic field emissions for pre-Amendments diagnostic ultrasound devices. The intensity values are derated. The derating algorithm is described in Appendix D of FDA's 1985 guidance document.

$I_{SPTA.3}$ = Derated Spatial Peak-Temporal Average Intensity
$I_{SPPA.3}$ = Derated Spatial Peak-Pulse Average Intensity
MI = Mechanical Index

Use	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)	MI
Peripheral Vessel	720	190	1.9
Cardiac	430	190	1.9
Fetal Imaging & Other*	94	190	1.9
Ophthalmic	17	28	0.23

* Abdominal, Intra-operative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic

Note: For purposes of acoustic output limits:

a. transesophageal, for non-cardiac use, and intra-luminal transducers are included in the Fetal Imaging and Other category;

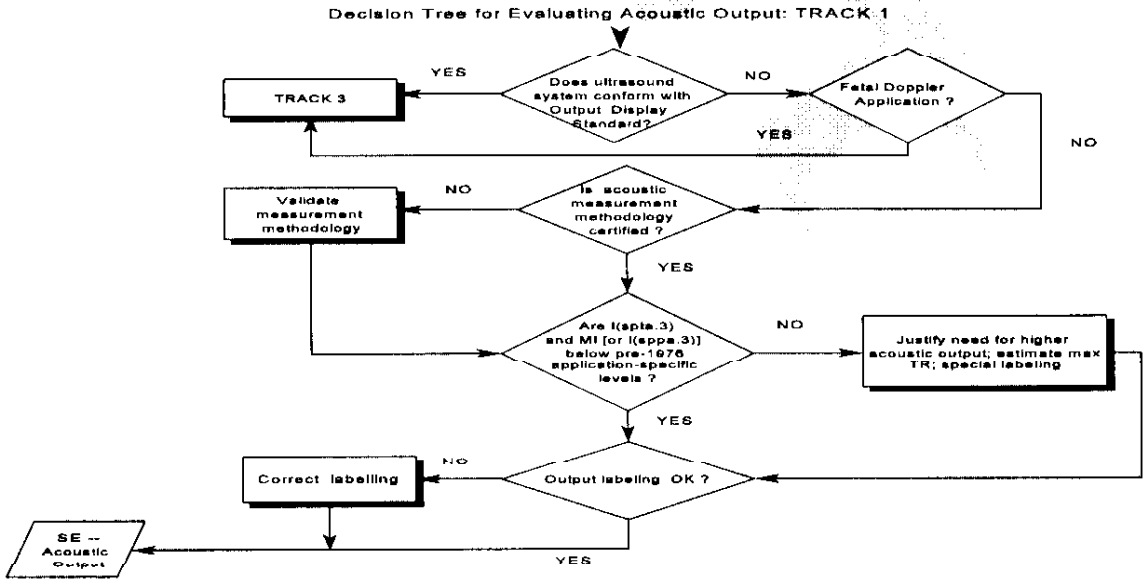
b. cardiac use includes transthoracic adult and pediatric uses as well as transesophageal adult and pediatric uses for visualization of the heart;

c. peripheral vessel use includes vessels of the neck; and

d. cephalic and transcranial are synonymous.

4 Track Flow Chart

The following is a flow chart illustrating the decision tree, with respect to acoustic output, for Track 1.



5 Track 1 Summary Table

A manufacturer following TRACK 1 should complete the table below for each system/transducer combination. For each mode/application checked in the table below, the appropriate acoustic output table should be completed.

Clinical Application	Operating Mode(s)							
	A	B	M	PWD	CWD	CD	Combined (Specify)	Other (Specify)**
Ophthalmic	_____	_____	_____	_____	_____	_____	_____	_____
Fetal Imaging & Other*	_____	_____	_____	_____	_____	_____	_____	_____
Cardiac, Adult & Pediatric	_____	_____	_____	_____	_____	_____	_____	_____
Peripheral Vessel	_____	_____	_____	_____	_____	_____	_____	_____

* Abdominal, Intra-operative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)

** Examples are: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

6. **TRACK 1 ACOUSTIC OUTPUT REPORTING TABLE**

6.1 Non-Auto-Scanning Mode

Transducer model: _____ Operating Mode: _____

Application(s): _____

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Maximum Value					
Associated Acoustic Parameters	$p_{r.3}$	(MPa)			
	W_o	(mW)			
	f_c	(MHZ)			
	z_{sp}	(cm)			
	Beam dimensions	x_{-6} (cm)			
		y_{-6} (cm)			
	PD	(usec)			
	PRF	(Hz)			
	EBD	(cm)			
Operator Controls	Control #1				
	Control #2				
	.....				
	.....				
	.....				
	.....				
	Control #n				

6. **TRACK 1 ACOUSTIC OUTPUT REPORTING TABLE**

6.2 Auto-Scanning Mode

Transducer model: _____ Operating Mode: _____

Application(s): _____

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Maximum Value					
Associated Acoustic Parameters	$p_{r.3}$ (MPa)				
	W_o (mW)				
	f_c (MHZ)				
	z_{sp} (cm)				
	Beam dimensions	x_{-6} (cm)			
		y_{-6} (cm)			
	PD (usec)				
	PRF (Hz)				
	EDS	Az. (cm)			
		Elev. (cm)			
Operator Controls	Control #1				
	Control #2				
	.....				
	.....				
	.....				
	.....				
	Control #n				

Notes for Track 1 Acoustic Output Tables

All table entries should be obtained at the same operating conditions that give rise to the maximum derated intensity or MI value in the first row.

These operating conditions should be specified.

Symbols used in the table are described below.

MI is the Mechanical Index. The value of MI at the position of $I_{SPPA.3}$ ("MI@$I_{SPPA.3}$") may be reported instead of "MI(maximum value)" if $I_{SPPA.3}$ is $\leq$ 190 W/cm^2.

$I_{SPTA.3}$ is the derated spatial-peak, temporal-average intensity (milliwatts per square centimeter).

$p_{r.3}$ is the derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under "MI".

$I_{SPPA.3}$ is the derated spatial-peak, pulse-average intensity (Watts per square centimeter). The value of $I_{PA.3}$ at the position of maximum MI ($I_{PA.3}$@MI) may be reported instead of $I_{SPPA.3}$ if MI > 1.0.

W_o is the ultrasonic power (milliwatts). For the operating condition giving rise to "$I_{SPTA.3}$", W_o is the total time-average power; for the operating condition subject to reporting under "$I_{SPPA.3}$," W_o is the ultrasonic power associated with the transmit pattern giving rise to the value reported under "$I_{SPPA.3}$".

f_c is the center frequency (MHZ). For MI and $I_{SPPA.3}$, f_c is the center frequency associated with the transmit pattern giving rise to the maximum value of the respective parameter. For $I_{SPTA.3}$, for combined modes involving beam types of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.

Z_{sp} is the axial distance at which the reported parameter is measured (centimeters).

x_{-6} and y_{-6} are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} is found (centimeters).

PD is the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.

PRF is the pulse repetition frequency (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.

EBD are the entrance beam dimensions for the azimuthal and elevational planes (centimeters).

EDS are the entrance dimensions of the scan for the azimuthal and elevational

planes (centimeters).

Measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency) should be provided.

TRACK 3 SPECIFIC INFORMATION

Track 3 is for diagnostic ultrasound systems that follow the Output Display Standard. Systems that include fetal Doppler applications, except for fetal heart rate monitors, should follow Track 3. Track 3 does not apply to systems for which a display would be required but which have fixed acoustic output. Under Track 3, acoustic output will not be evaluated on an application-specific basis, but the maximum derated I_{SPTA} must be $\leq$ 720 mW/cm^2 and either the maximum MI must be $\leq$ 1.9 or the maximum derated I_{SPPA} must be $\leq$ 190 W/cm^2. An exception is for ophthalmic use, in which case the TI (for display) = max.(TIS_as, TIC), and is not to exceed 1.0; $I_{SPTA.3} \leq$ 50 mW/cm2, and MI $\leq$ 0.23. See Sec. 4 for a logic flow chart.

1 Track 3 Acoustic Output Reporting

The Track 3 approach is based upon conformance with the Output Display Standard. This approach eliminates the application-specific comparison of acoustic output to pre-Amendments levels.

1.1. Summarize the operating mode possibilities for each system/transducer combination by completing the form given in Sec. 5. For each possible transducer/mode identified, specify the target range of values for the MI or I(SPPA.3) and I(SPTA.3), and an estimated range of TI's, under the operating conditions that maximize these quantities, noting that the upper bound must not be greater than the maximum values given at the top of this page. Also provide the engineering basis for the range of values specified (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers).

1.2. Provide certification (I) that measurements of acoustic output display indices - the Thermal Index (TI) and the Mechanical Index (MI) - will be made per Section 6 of the Output Display Standard entitled "Measurement Methodology for Mechanical and Thermal Indices" and (ii) that information supplied in the 510(k) will be for maximum TI and MI values.

1.3 If the manufacturer wishes to submit the 510(k) Special Report as part of the 510(k), it should be included as a completely separate section and this election should be noted in the 510(k) cover letter. The 510(k) Special Report should follow the format described in Appendix G.

1.4 Specify the default setting levels as a percentage of the maximum levels and the rationale for selecting these default values. See Section 5 of the Output Display Standard. Note that a default setting yielding maximum acoustic output would not be considered appropriate for implementing ALARA.

1.5 Provide a justification for any Thermal Index that exceeds a value of 6.0.

1.6 If no system/transducer combination is capable of exceeding either a

TI of 1 or an MI of 1 in any operating mode, then completion of the Track 3 acoustic output tables in Sec. 6 is not necessary. However, in their place the maximum values of the derated I_{SPTA}, TI, MI, and derated I_{SPPA} associated with the maximum MI, should be specified. Details of the calculations should be included in the Device Master Record.

2 Track 3 - Acoustic Output Labeling in the Operator's Manual

2.1 Provide tables of the maximum acoustic output indices for each possible system/transducer/mode combination, per Secs. 5 and 6. The tables for the 510(k) submission need not be completed, but the different table formats to be used should be submitted, along with the description of symbols. The labeling (submitted in the 510(k) Special Report) for the marketed device, however, should contain the full set of complete acoustic output tables, along with the corresponding operating conditions and the measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency).

.

Three examples for the Track 3 Acoustic Output Reporting Tables are given at the end of this section. These are provided to illustrate the use of the four footnotes (a, b, c, #).

2.2 Provide an explanation of the real-time display features and controls of the system, including default settings and setting levels expressed as a percentage of the maximum levels (see Sec. 1.4). Provide suggestions on how to use these features and controls to follow the ALARA principle. Note: If the intended uses include neonatal cephalic, then the provisions of the Output Display Standard are interpreted to mean that all three thermal indices (TIS, TIB, TIC) should be available for real-time display. In this regard, please see page 39 in the AIUM publication, "Medical Ultrasound Safety" (AIUM, Laurel, MD, 1994).

2.3 Provide the display accuracy and measurement precision. See Sections 4.2, 4.2.1, and 6.4 of the Output Display Standard.

2.4 If **no** system/transducer combination in a Track 3 device is capable of exceeding either a TI of 1 or an MI of 1 in any operating mode, then provide the maximum values, for each transducer, of the derated I_{SPTA}, TI, MI, and derated I_{SPPA} associated with the maximum MI. See Sec. 1.6.

3 Track 3 Education Program

3.1 Provide an ALARA education program for the clinical end-user that covers the subjects listed below. ALARA is an acronym for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at an output that is as low as reasonably achievable. This education program should include explanations of: 1. the basic interaction between ultrasound and matter, 2. the possible biological effects, 3. the derivation and meaning of the

Indices, 4. a recommendation to use and the need for following the ALARA principle in all studies, and 5. clinical examples of specific applications of the ALARA principle. A document published by the AIUM, "Medical Ultrasound Safety," is acceptable to FDA as meeting the generic content of the educational program. The manufacturer also should provide information specific to its device regarding ALARA.

3.2 Minimum Requirements for Educational Material for Track 3 Devices

3.2.1 Bioeffects and Biophysics of Ultrasound Interactions--
- Brief description of ultrasound, diagnostic frequencies, energy levels
- Brief description of the change in policy which requires user education
- Short history of ultrasound use and safety record
- Potential hazards at high output levels
- Biological effect mechanisms--Thermal, Mechanical
- Exposure-effect studies (range of outputs)
- Risk versus benefit
- Present state of output levels--higher than historical levels
- Proposed indices as indicators of thermal and mechanical effects

3.2.2 Thermal Mechanisms--
- Describe thermal bioeffects--temperature rise
- Tissue type (soft, bone, fluid) and relative absorption
- Transducer type (frequency, focusing) and relationship to exposure
- Attenuation, absorption, scattering mechanisms in different tissue types
- Spatial volume of insonified tissue (at focus, or elsewhere)
- Homogeneity of tissue in insonified volume (effects of layering)
  - --soft tissue
  - --bone tissue (fetal, skull, other)
  - --fluids, gas

3.2.3 Nonthermal Mechanisms
- Describe mechanical effects--cavitation & role of bubbles
- Factors which produce cavitation:
  - --pressure (compressional, rarefactional)
  - --frequency
  - --beam focusing
  - --pulsed/continuous
  - --standing waves
  - --boundaries
  - --type of material and ambient conditions
- Types of cavitation:
  - --stable and inertial cavitation
  - --microstreaming
  - --nucleation sites
- Threshold phenomena for different types of tissues
- Bioeffects data on animals (lung hemorrhage, intestinal hemorrhage)

3.2.4 Benefits of Ultrasound vs. Risk
- Benefits of use

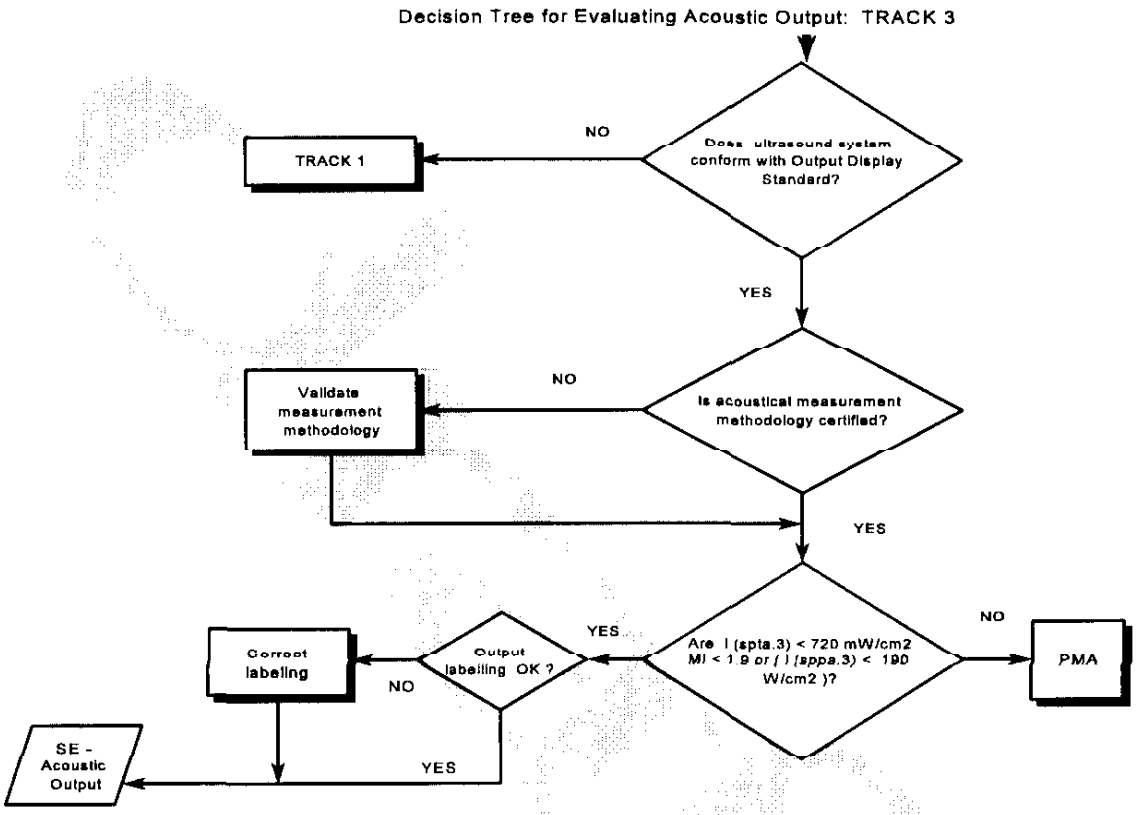
-Risk of use
-Risk of not using ultrasound
-Increase in risk as acoustic output increases
-Increase in diagnostic information as acoustic output increases
-Increase in responsibility for user at higher output levels
-The ALARA principle
  --controlling energy
  --controlling exposure time
  --controlling scanning technique
  --controlling system setup
  --effects of system capabilities
  --effects of operating mode (learn to distinguish)
  --effects of transducer capabilities

3.2.5 The Output Display Standard
-Purpose: To display exposure indices
-Mechanical Index (MI)
-Thermal Index (TI)
  --Soft Tissue Thermal Index (TIS)
  --Bone Thermal Index (TIB)
  --Cranial Bone Thermal Index (TIC)
-Thresholds for display of indices
(e.g., if system can exceed TI or MI of 1.0)
-System display levels
(e.g., minimum TI displayed, minimum MI displayed, display increments)
-Explanation of the meaning of the TI and MI
  --threshold bioeffect levels vary depending on tissue type
  --bioeffect levels vary depending on frequency, pressure

3.2.6 Practicing the ALARA Principle
-How to implement ALARA by using the TI and MI indices
-Knowledge of system controls versus acoustic output
  --Overall gain and TGC versus increasing output
  --Dynamic range and post-processing versus increasing output
-Knowledge of system applications versus output
  --selection of appropriate range for task
-Knowledge of transducer effects on output
  --frequency
  --focusing
  --pulse length
  --dwell time (scanned versus unscanned)
-Knowledge of system operating mode versus output
  --B mode
  --Doppler (spectral, color flow, Power Doppler)
  --M mode
-Control exposure time
-Use the minimum possible to obtain information
-Clinical application examples--which indices are most important?:
  --fetal, cranial
  --fetal, Doppler
  --Adult thyroid
  --Adult carotid Doppler

4 Track Flow Chart

The following is a flow chart illustrating the decision tree, with respect to acoustic output, for Track 3.



5 Track 3 Summary Table

For a Track 3 submission, complete the table below for each transducer/mode combination. Indicate with "yes" the transducer/mode combinations for which the maximum displayed MI or TI index is greater than 1.0. For each transducer/mode combination marked yes, a Track 3 acoustic output table should be completed. Also, see Sec. 2.4.

OPERATING MODE	TRANSDUCER MODEL					
B-mode						
M-mode						
Pulsed Doppler						
CW Doppler						
Color Flow						
Combined (specify)						
Other (specify)						

For reporting purposes, the following mode definitions and reporting rules apply:

B Mode: No other modes active.
Only MI (when > 1.0) need be reported for this mode.

M Mode: May include simultaneous B mode.
PW Dop.:
CW Dop.: In duplex modes, report largest displayed TIS (scanned or non-scanned) if > 1.0.

Color Flow: May include simultaneous Color Flow M-mode, B-mode and M-mode.
In combined modes, report largest displayed TIS (scanned or non-scanned) if > 1.0.

Other combined modes: Need only be reported as a separate mode if the largest formulation of TIS, TIB or TIC (if there is an applicable intended use; e.g., transcranial or neonatal cephalic) is greater than the corresponding value reported for all constituent modes.

TIC need not be reported if the probe is not intended for transcranial or neonatal cephalic use.

6. TRACK 3 ACOUSTIC OUTPUT REPORTING TABLE

(Provide data where maximum displayed index value exceeds 1.0.)

Transducer Model:_____ Operating Mode: _____

Index Label			MI	TIS			TIB (non scan)	TIC
				Scan	non-Scan			
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value								
Assoc. Acoustic Param.	$p_{r.3}$	(MPa)						
	W_o	(mW)						
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHZ)						
	Dim. of A_{aprt}	X (cm)						
		Y (cm)						
Other Info.	PD	(usec)						
	PRF	(Hz)						
	$p_r@PII_{max}$	(MPa)						
	$d_{eq}@PII_{max}$	(cm)						
	Focal Length	FL_x (cm)						
		FL_y (cm)						
	$I_{pa.3}@MI_{max}$	(W/cm^2)						
Operator Controls	Control #1							
	.....							
	Control #n							

Footnotes: a) Display of this index is not required for this operating mode; see Sec. 4.1.3.1 of the Output Display Standard (NEMA UD-3).
b) This probe is not intended for transcranial or neonatal cephalic uses.
c) This formulation for TIS is less than that for an alternate formulation in this mode.
No data are provided for this operating condition since the maximum index value is not reported for the reason listed.

Notes for Track 3 Acoustic Output Table

All table entries should be obtained at the same operating conditions that give rise to the maximum "Index Value" in the second row.

These operating conditions should be specified.

Symbols used in the Table are described below.

MI is the Mechanical Index.

TIS_{scan} is the Soft Tissue Thermal Index in an auto-scanning mode.

$TIS_{non\text{-}scan}$ is the Soft Tissue Thermal Index in a non-auto-scanning mode.

TIB is the Bone Thermal Index.

TIC is the Cranial Thermal Index.

A_{aprt} is the area of the active aperture (square centimeters).

$p_{r.3}$ is the derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under "MI".

W_o is the ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window (milliwatts).

$W_{.3}(z_1)$ is the derated ultrasonic power at axial distance z_1.

$I_{TA.3}(z_1)$ is the derated spatial-peak, temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).

z_1 is the axial distance corresponding to the location of $\max[\min(W_{.3}(z), I_{TA.3}(z) \times 1\ cm^2)]$, where $z \geq z_{bp}$ (centimeters).

z_{bp} is $1.69(A_{aprt})^{½}$.

For MI, z_{sp} is the axial distance at which $p_{r.3}$ is measured; for TIB, z_{sp} is the axial distance at which TIB is a maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).

$d_{eq}(z)$ is the equivalent beam diameter as a function of axial distance z, and is equal to $[(4/\pi)(W_o/I_{TA}(z))]^{½}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters).

f_c is the center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the maximum reported

value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.

Dim. of A_{aprt} are the active aperture dimensions for the azimuthal and elevational planes (centimeters).

PD is the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.

PRF is the pulse repetition frequency (Hz) associated with the transmit pattern giving rise to the reported value of MI.

p_r @ PII_{max} is the peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum (megapascals). (See Section 6 of the Standard for Real-Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, entitled "Measurement Methodology for Mechanical and Thermal Indices", § 6.2.4.1.).

d_{eq} @ PII_{max} is the equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum (centimeters). (See Section 6 of the Standard for Real-Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, entitled "Measurement Methodology for Mechanical and Thermal Indices", § 6.2.5.1.).

FL is the focal length, or azimuthal and elevational lengths, if different (centimeters).

$I_{PA.3}$ @ MI_{max} is the derated pulse average intensity (Watts per square centimeter) at the point of maximum reported MI.

Measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency) should be provided.

Examples for Track 3 Acoustic Output Reporting Tables

The next three pages contain example output tables to illustrate the use of the four footnotes (a, b, c, #). A check mark indicates that the box should be filled in with the appropriate value; a dash means that no value is required because of either scan/non-scan or aperture size considerations.

With regard to the third example, color flow and M-mode, the use of footnote c) is shown. Note that if the M-mode TIS were greater than the color flow TIS, then footnote c) would appear under TIS(scan), and the M-mode TIS value would be listed in the appropriate TIS(non-scan) box. Therefore, it is important to list under "Operating Mode" all included modes for proper interpretation of the tabulated values.

Example 1

TRACK 3 ACOUSTIC OUTPUT REPORTING TABLE

(Provide data where maximum displayed index value exceeds 1.0.)

Transducer Model: _____ Operating Mode: B-mode

Index Label			MI	TIS			TIB (non scan)	TIC
				scan	non-scan			
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value			1.5	(a)	-	-	-	(a)
Assoc. Acoustic Param.	$p_{r.3}$	(MPa)	✓					
	W_o	(mW)		#	-		-	#
	min of $[W_{.3}(z_1)$, $I_{TA.3}(z_1)]$	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	✓				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHZ)	✓	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#				#
		Y (cm)		#	-	-	-	#
Other Info.	PD	(usec)	✓					
	PRF	(Hz)	✓					
	$p_r@PII_{max}$	(MPa)	✓					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{pa.3}@MI_{max}$	(W/cm²)	✓					
Operator Controls	Control #1							
	.....							
	Control #n							

Example 2

TRACK 3 ACOUSTIC OUTPUT REPORTING TABLE

(Provide data where maximum displayed index value exceeds 1.0.)

Transducer Model:_____ Operating Mode: _____Pulsed Doppler

Index Label			MI	TIS			TIB (non scan)	TIC
				scan	non-scan			
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value			(a)	-	-	<1	2.0	<1
Assoc. Acoustic Param.	$p_{r.3}$	(MPa)	#					
	W_o	(mW)		-	-		✓	✓
	min of $[W_{.3}(z_1)$, $I_{TA.3}(z_1)]$	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)	#				✓	
	$d_{eq}(z_{sp})$	(cm)					✓	
	f_c	(MHZ)	#	-	-	#	✓	✓
	Dim. of A_{aprt}	X (cm)		-	-	#	✓	✓
		Y (cm)		-	-	#	✓	✓
Other Info.	PD	(usec)	#					
	PRF	(Hz)	#					
	p_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					✓	
	Focal Length	FL_x (cm)		-	-	#		✓
		FL_y (cm)		-	-	#		✓
	$I_{pa.3}$@ MI_{max}	(W/ cm^2)	#					
Operator Controls	Control #1							
	.....							
	Control #n							

Example 3

TRACK 3 ACOUSTIC OUTPUT REPORTING TABLE

(Provide data where maximum displayed index value exceeds 1.0.)

Transducer Model: _____ Operating Mode: Color Flow (includes M-mode)

Index Label			MI	TIS			TIB (non scan)	TIC
				scan	non-scan			
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value			(a)	2.0	-	(c)	3.0	(b)
Assoc. Acoustic Param.	$p_{r.3}$	(MPa)	#					
	W_o	(mW)		✓	-		✓	#
	min of $[W_{.3}(z_1)$, $I_{TA.3}(z_1)]$	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)	#				✓	
	$d_{eq}(z_{sp})$	(cm)					✓	
	f_c	(MHZ)	#	✓	-	#	✓	#
	Dim. of A_{aprt}	X (cm)		✓		#	✓	#
		Y (cm)		✓	-	#	✓	#
Other Info.	PD	(usec)	#					
	PRF	(Hz)	#					
	p_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					✓	
	Focal Length	FL_x (cm)		✓	-	#		#
		FL_y (cm)		✓	-	#		#
	$I_{pa.3}$@ MI_{max}	(W/ cm^2)	#					
Operator Controls	Control #1							
	.....							
	Control #n							

Appendix A

Doppler Sensitivity

As specified in General Information, Sec. 6.1.3, transducers that may operate in Doppler modes should be tested for sensitivity and the results of this testing should be reported in the 510(k) or **510(k) Special Report**.

Doppler sensitivity is defined as the minimum detectable Doppler signal, for a given center frequency and acoustic power, reflected from flowing blood-equivalent scatterers deep within tissue. A measure of Doppler sensitivity is the maximum tissue depth at which a Doppler signal of known strength is detectable by a given Doppler instrument. The deeper in the body that a signal can be detected, the more sensitive the device is said to be.

An alternative definition of sensitivity is a measure of the signal-to-noise ratio of the detected Doppler signal reflected by blood-equivalent scatterers at different depths in tissue, or a tissue-equivalent material, for a specific Doppler shift frequency and acoustic power.

Suggested guide for sensitivity measurements:

A. Test Materials

For measuring Doppler sensitivity, the use of a physiologically relevant test method is recommended. The method should include the following materials:

1. A phantom with uniformly attenuating tissue-equivalent medium (with attenuation of approximately 0.5 dB/cm-MHZ), in which a simulated blood vessel is embedded at a sloping angle, or several different simulated vessels are embedded at different depths (string phantoms and electronic phantoms are not recommended);

2. A blood-mimicking fluid of known properties (i.e., fluid type, particle type and size, concentration, backscatter intensity, viscosity, etc.); this fluid and its scatterers should resemble human blood as closely as possible in particle size and backscatter levels (ref. 1); and

3. A means to vary fluid flow in the vessel; e.g., pump, gravity feed, etc.

The simulated test vessel should have a cross-sectional diameter no larger than 5 mm. The test vessel should either be sloping in a tissue-mimicking matrix, or several simulated vessels could be placed horizontally, at different depths in the phantom. The use of amorphous (slurry-like) TM material could be used to make this configuration easier to obtain. Additional measurements using larger diameter vessels (e.g., 10 mm and 15 mm) would be useful, but not required.

B. Methods

A suggested measurement procedure is described below. Reasonable variations and/or improvements in this procedure are acceptable.

1. With acoustic power set at maximum for a given transducer, obtain a clean Doppler flow signal from the blood-mimicking fluid at zero depth, for a velocity in the middle of the instrument's velocity range. Measure the maximum depth at which the Doppler signal can be detected both on the Doppler display and by the audible Doppler signal. Since the phantom attenuation is known in dB/cm-MHZ, the maximum depth of penetration can be expressed in decibels. Record the maximum depth of penetration (in both distance and dB) for mid-range velocity, v_2.

2. Repeat these measurements for the minimum and maximum detectable velocities in the Doppler velocity range for the Doppler instrument. The first value to measure is the maximum depth at which the lowest velocity will be detected and record this value as v_1. Proceed to find the maximum depth at which the maximum system velocity is detected and record that value as v_3.

3. For a more quantitative measurement, the user may consider the use of an RMS voltmeter to measure the output Doppler signal (Ref. 1). Plot the signal-to-noise ratio versus depth in the tissue-mimicking material for each selected velocity setting (low, medium, high), indicating the noise-equivalent cutoff. The cutoff point defines the maximum sensitivity for the given transducer and acoustic output setting configuration.

References:

1. Boote, E.J., Zagzebski, J.A., "Performance Tests of Doppler Ultrasound Equipment with a Tissue and Blood-Mimicking Phantom", J. Ultrasound in Medicine, 7:137-147, 1988.

Appendix B

RELATED GUIDANCE DOCUMENTS

Title	Date
"510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices"	12/85
"Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"	8/29/91
"Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities"	4/96
"Labeling: Regulatory Requirements for Medical Devices" (HHS Publication FDA 89-4203)	1989
Medical Alert on latex products, "Allergic Reactions to Latex-Containing Medical Devices"	3/29/91
ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	1993
Deciding When to Submit a 510(k) for a Change to an Existing Device	1997
DRAERD Kit Policy	*****

Appendix C

Administrative Forms

510(k) Summary/Statement Certification

Re: K_____

CHECK ONLY ONE:

☐ 1. **510(k) Summary.** Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 2. **510(k) Statement.** I certify that, in my capacity as _____, of_____(company), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____

[*Signature**]

_____

[*Typed or Printed Name*]

_____

[*Date*]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
(as required by 21 CFR 807.87(j))

I certify that, in my capacity as _____ of _____(company name), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

_____ _____
(signature*) (date)

_____ _____
(typed name) (510(k) number)

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative **(Specify)**										
Intra-operative Neurological										
Pediatric										
Small Organ **(Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Appendix D

Summary of Statistical Reporting in the 510(k) and Special 510(k) Report

There are five areas of the submission in which a statistical analysis of measurement or performance data may be necessary.

1. Specification of clinical measurement accuracy. See General Information, Secs. 6.1.2 and 7.1.4 of this Guidance.

2. Specification of measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency). See Track 1, Sec. 2.1 and Track 3, Sec. 3.1 of this Guidance. In this regard, a good description of the various potential sources of random and systematic uncertainties for hydrophone measurements can be found in, R.C. Preston, D.R. Bacon, and R.A. Smith, "Calibration of medical ultrasonic equipment - procedures and accuracy assessment," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, vol. 35, no. 2, pp. 110-121, 1988.

3. Specification of statistical sampling plan used to insure that the acoustic outputs of production units do not exceed appropriate pre-Amendments output levels in Track 1, Sec. 3. See Appendix G, Section E6, (and Track 1, Sec. 1.2 and Track 3, Sec. 1.3) of this Guidance.

4. Specification of display accuracy, as defined in Section 2.1 of the Output Display Standard, and required in Section 4.2.1 of the Output Display Standard. See Track 3, Sec. 2.3 of this Guidance.

5. Specification of measurement precision of center frequency, acoustic power, and peak rarefactional pressure, as described in Section 6.4 of the Output Display Standard. See Track 3, Sec. 2.3 of this Guidance.

Appendix E

Deciding If System and Transducer Modifications Require Additional 510(k) Premarket Notifications or Add-To-Files

See Center guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device."

A. The addition or modification of transducers to a particular system will not require a new 510(k) if all of the following conditions are met:

1. The system is already the subject of a submitted and cleared 510(k);

2. Indication(s) for use and mode(s) of operation are unchanged;

3. Acoustic output of each new or modified transducer is below the limits in the enclosed tables for the respective indication(s) (Track 1) or are below $I_{SPTA.3}$ =720 mW/cm^2 and either MI=1.9 or $I_{SPPA.3}$ =190 W/cm^2 (Track 3); and **OPHTHALMIC LIMITS ?*****

4. Acoustic output is measured according to the 510(k) Guide and recorded according to the procedures in the 510(k) Guide; these procedures are included in the Device Master Record or Design History File, and the results are included in the Device History Record, as part of the Good Manufacturing Practices (GMPs) for that device. This condition should be met for changes that affect the output of any transducer intended for use with the system. In addition, the Master Record should adequately document minor changes not affecting the indications for use or acoustic output. These files will be reviewed periodically under inspection authority of the Food, Drug, and Cosmetic Act.

   If measurement technology different from that defined in the 510(k) Guide is used to document acoustic output, a 510(k) premarket notification will be necessary.

B. Modifications to a diagnostic ultrasound system that has a previously cleared 510(k) will not require a new 510(k) if the indications for use and the ultrasound generator, transducer(s), controls, and signal processing technologies are unchanged; no system functions are added; and no claims of added effectiveness are made. CDRH still reserves its discretion to require a 510(k) in selected situations.

C. A device that enters the market using the process described above cannot be used as a predicate for a future submission.

D. New Indications for Use

New clinical applications represent new indications for use and therefore require a new 510(k). This determination is generally based on clinical features. Does the new application provide new clinical information? Does it provide a new interpretation of existing information? If the answer is yes, generally a new 510(k) is appropriate. Several examples of recent new

applications and the data necessary for a 510(k) follow. Generally, a new indication will need the following information:

1. A description of the new feature including clinical use and theory of operation;

2. A discussion of any new means of operation necessary to use the new application;

3. A discussion of the acoustic output consequences (TI, MI, $I_{SPTA.3}$, etc.) resulting from use of the new application;

4. A demonstration of the clinical utility of the new application; and

5. A demonstration clinical study and interpretation by a Radiologist that demonstrates the competency of the device to perform the new task and a discussion of the minimum performance requirements necessary for a device to properly perform the new task.

Examples of new applications that need new 510(k)s are: 3-D imaging, Power or Amplitude Doppler Imaging, and Musculo-Skeletal (superficial) Imaging.

Example 1--Three-Dimensional Imaging, Reconstruction, and Volume Computation

For devices that display three-dimensional ultrasound data, the manufacturer should submit their data collection and data display method(s). If the system uses lenses or other techniques that simulate three-dimensions, this should be stated clearly and the Labeling should state that no three-dimensional volume data is collected or displayed. Conversely, if the system is a true 3-dimensional system that collects data stored in a 3-dimensional array and reconstructs and/or renders the final 3-D image, then these reconstruction and rendering methods should be described. The manufacturer should clearly state if a three-dimensional array is created from original data or if several 2-dimensional arrays are interpolated to construct a three-dimensional data volume. A description (simplified flow chart) of the sampling and reconstruction algorithm should be included.

A demonstration of device reconstruction accuracy can be demonstrated by submitting 3-D reconstruction data from an appropriate phantom. The phantom should be tissue-mimicking and should include geometrically-regular objects (e.g., spheres, ellipses, cylinders, cones) whose dimensions are known and whose positions can be tested at different depths within a test volume. The objects in the phantom should include small sizes and low contrast levels such that they demonstrate the device reconstruction resolution limits. Note that the reconstruction resolution is different from the system resolution.

The measurement data should demonstrate that object(s) of known dimensions and contrast can be accurately reproduced in a three-dimensional image. The image measurements and relative dimensions of the object(s) should correspond to those of the original object for a range of object sizes. If the manufacturer claims volume computation capability, data should be supplied that compute the

volume for a range of reconstructed test objects, within the phantom, of known size (from largest to smallest), giving the calculated volume and associated error compared to the known object volume. This computation should also be performed for objects of low contrast, to demonstrate how the system error is affected by ill-defined contours.

If the manufacturer claims a specific level of reconstruction resolution, this should be demonstrated by data and images of the smallest objects the system can reconstruct for each of several low contrast levels.

Example 2-- **Amplitude Doppler**

The filing of a 510(k) submission is required for any diagnostic ultrasound system adding amplitude Doppler mode.

The following information should be supplied:

- a concise technological description of your version of amplitude Doppler modality (include trade name and summary description of algorithms used);

- a detailed comparison between the subject and predicate modalities (i.e., intended use, algorithms, technological characteristics, performance specifications, general claims) with all differences highlighted;

- acoustic output reporting associated with amplitude Doppler mode;

- the results of the measured Doppler sensitivities of the system/transducer combination for several depths;

- a discussion of the basis for any claim of improved imaging or reduction of an artifact;

- software information (include version number; structural chart; hazard analysis; system/software requirements; design and development process; verification and validation description; test results, reports and summaries; certification statement);

- adequate descriptive information and instructions for use in the product labeling, including a discussion of any new artifacts; and

- sample clinical images of each area of the body intended to be imaged together with a professional's interpretation of the images.

Example 3-- Musculo-Skeletal (superficial) Imaging

Recent advances in data processing have allowed ultrasound devices to easily image areas that heretofore have been difficult. Imaging of superficial tendons, ligaments, and muscles are one such example.

Musculo-Skeletal imaging has been performed for some time. It was limited to deep structures and had limited resolution. The advent of high definition

imaging has now allowed the imaging of superficial structures (1.5 cm or less). For purposes of clarity, we are calling the older imaging "musculo-skeletal (conventional)" and the newer method "musculo-skeletal (superficial)." We regard the new method as a new clinical application and subject to a 510(k) submission.

Appendix F

Exemption from Reporting Under 21 CFR 1002

Appendix G

Format and Content of Diagnostic Ultrasound 510(k) Special Report

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

General Information

Purpose:

Manufacturers and importers of diagnostic ultrasound equipment are subject to the requirements promulgated under Subchapter C - Electronic Product Radiation Control of the Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act), as well as the medical device requirements under the Medical Device Amendments and the Safe Medical Devices Act. Applicable radiation reporting regulations are contained in Title 21 CFR, Part 1002.

Currently, manufacturers are exempt from reporting under Part 1002 of the regulations if the 510(k) requirements are met. This guide is intended to assist manufacturers in providing final measurement data and product labeling information, based on their production devices, following 510(k) clearance.

Use of this Guide:

Retain this guide for photocopying (or formatting for word processing) for use in filing all reports in the future. When the report is completed, make a copy and retain the copy in your Device Master Record.

Submission of Reports:

The report should reference your 510(k) number and be submitted, in duplicate, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center
9200 Corporate Blvd.
Rockville, Maryland 20850

FOI Notice:

The acoustic output forms submitted as part of this report may be subject to public disclosure in accordance with the Freedom of Information Act, 5 U.S.C. 552, and any other applicable statute or agency regulation.

A. REPORT IDENTIFICATION:

A1. Date of 510(k) Special Report:

A2. Date and Control Number of 510(k) Notice (if assigned):

B. IDENTIFICATION OF FIRM

B1. Manufacturer's Name:

Address:

Corresponding Official:

Title:

Address:

Signature:
Telephone:

B2. U.S. Agent (if manufacturer is overseas)

Name/Title/Firm:

Address:

Telephone:

B3. Importer Name:

Address:

Contact Person:

Telephone:

B4. Factory Location:

C. IDENTIFICATION OF MODEL BEING REPORTED:

Brand	Model Number	Transducers

D. CLINICAL APPLICATIONS/OPERATING MODES (Track 1 only):

Mark, as appropriate.

	A	B	M	PWD	CWD	CD	Combined (specify)	Other (specify)**
Ophthalmic	___	___	___	___	___	___	_____	_____
Fetal Imaging & Other*	___	___	___	___	___	___	_____	_____
Cardiac Adult & Pediatric	___	___	___	___	___	___	_____	_____
Peripheral Vessel	___	___	___	___	___	___	_____	_____

* Abdominal, Intra-operative, Pediatric, Small organ (Breast, Thyroid, Testes, etc.), Neonatal Cephalic, Adult Cephalic

**Examples are: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

E. MAXIMUM ACOUSTIC OUTPUT LEVELS

E1. Measured values from production units:

Provide the maximum derated SPTA intensity values and Mechanical Index (or derated SPPA intensity) values obtained from production units, as determined according to Section E6 below. For Track 1, provide this information for each system/transducer/mode/application combination (i.e., one set of values for each of the items checked in Section D). For Track 3, provide this information for each system/transducer/mode combination.

E2. Number of units tested and percentage of production lot:

E3. Estimate of measurement uncertainties:

E4. Describe the operating conditions used to obtain the measured acoustic output:

E5. Did the operating conditions result in maximizing output? If not, please explain and provide reasons for equivalence:

E6. Provide the statistical plan and protocol used to ensure that the appropriate intensity and index values are not exceeded [I(SPTA.3) values for Track 1, see Track 1, Sec.2; I(SPTA.3)=720 mW/cm^2 for Track 3; MI=1.9 (0.23 for ophthalmic) for both tracks]: ******ophthalmic reqs to be added

Firms are not required to conduct 100% sampling. If however, testing is performed on all devices to be shipped and it is assured that the acoustic output of each device tested will not exceed maximum specified

levels following the guidelines described in General Information, Sec. 5, paragraphs 3 and 4, then the process for determining the measurement uncertainty shall be provided in the 510(k) and the data establishing the measurement uncertainty shall be available for inspection under GMP.

If 100 percent sampling is not done, then the sampling plan should provide reasonable statistical assurance that production units will not exceed the maximum acoustic output levels specified in the guidance. This should be accomplished by following a statistical technique known as "one-sided tolerance for normal distributions" (see section 2-5 on page 2-13 and Table A-7 on page T-14 of EXPERIMENTAL STATISTICS by M.G. Natrella, NBS Handbook 91). In applying this technique, the sample size should be not less than three units. This procedure has the following formulation:

$$L \geq \overline{X} + Ks$$

where:

- L is the $I_{SPTA.3}$ or MI (or $I_{SPTA.3}$) limit
- $\overline{X}$ is the mean of the measured values
- s is the standard deviation of the measured values
- K is a value found in Table A-7, and is a function of
- γ (confidence level), P (the proportion of the distribution less than ($\overline{X}$ + Ks)), and n (sample size).

The choice of γ, P, and n is at the manufacturer's discretion. However, the choice of γ, P, and n should be documented and justified in the GMP process and the Device Master Record. The values of $\overline{X}$, s, γ, P, and n should be provided in this appendix.

An example of applying this procedure to a population of ultrasound transducers is given in M.C. Ziskin, "Measurement of Uncertainty In Ultrasonic Exposimetry," Ultrasonic Exposimetry, M.C. Ziskin and P.A. Lewin, eds. (CRC Press, Boca Raton, Florida, 1993) pp. 409-443, with the substitution of Table A-7 from NBS Handbook 91 in place of Table 2 provided in the Ziskin reference.

Note 1: In computing the standard deviation s, the hydrophone measurement uncertainty does not have to be taken into account if it is less than $\pm$ 30% for intensity or $\pm$ 15% for MI. However, if the hydrophone measurement uncertainty exceeds these values, then the guidance levels should be reduced accordingly, as described in General Information, Sec. 5, paragraphs 3 and 4.

Note 2: Another reference for the one sided tolerance tables is Gerald J. Hahn and William Q. Meeker, Statistical Intervals, A Guide for Practioners (John Wiley and Sons, New York 1991) The ISBN number is 0-471-88769-2. See tables A.12c and d, on pages 314 and 315. In these tables, $\gamma=1-\alpha$.

F. DOPPLER SENSITIVITY

Provide data validating the Doppler sensitivity specification (see General Information, Sec. 6.1.3), if not provided in the original submission.

G. LABELING/USER INFORMATION

Provide a copy of all labeling pages that have significant changes in content only from that submitted in the 510(k) submission and certify that no other significant content changes have occurred; i.e., do not include pages that have changes in format or pagination.

H. GMP TEST PLAN

Provide a brief description of testing for acoustic output (frequency of testing, percentage of production, uncertainty, etc.):

Cleaning and Disinfection

disinfection is a two step process: a cleaning step followed by a
is incorrect.

CLEANING

scanning gel, etc.) from the device. The device is first cleaned with a compatible detergent then rinsed to remove residue. Enzyme cleaners and Disinfection solutions are not intended to be cleaning agents. Reusable devices should be designed to allow

disinfection procedures are likely to be ineffective.

DISINFECTION OR STERILIZATION

disinfection required for a device is dictated by the type of tissue it will contact during use. Non-critical, semi-critical, and critical

the use of the device. For this guidance, non-critical applications are those where the device contacts only intact skin; semi-critical applications are

those where the device contacts blood, compromised tissue, or is used in a sterile field.

low-level disinfected between patient use. Probes used in semi-critical applications should be high-level disinfected and the use of a sheath

disinfected, at a minimum, and must be used with a sterile sheath.

There are several special situations:

Neurosurgical use: Operative devices that contact brain tissue should not be sterilized using liquid
is neuro-toxic. These probes should be used with a sheath that is pyrogen-free. Note: If the probe is used on a patient with Creutzfeld-Jacob Disease and the sheath breaks, the probe may be disinfection procedures (see CDC guidance).

2.
and vaginal probes where the sheath can be surgically clean.

3. sterilants,
liquid sterilization is recommended only for situations in which ETO gas

For further information see CDRH's document titled "Labeling Reusable Medical